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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte STEVEN SPENCER and RICHARD GUNDERSON

Appeal 2015-004113[1]
Application 13/571,552[2]
Technology Center 3700

Before HUBERT C. LORIN, KENNETH G. SCHOPFER, and AMEE A. SHAH, *Administrative Patent Judges*.

SCHOPFER, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the Examiner's Final rejection of claims 1–12 and 14–20. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM-IN-PART.

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[1] Our decision references Appellants' Appeal Brief ("Appeal Br.," filed Aug. 15, 2014) and Reply Brief ("Reply Br.," filed Feb. 20, 2015), and the Examiner's Answer ("Ans.," mailed Dec. 22, 2014) and Final Office Action ("Final Act.," mailed Mar. 21, 2014).

[2] According to Appellants, the real party in interest is Boston Scientific SciMed, Inc. Appeal Br. 4.

BACKGROUND

According to Appellants, "the disclosure is directed to self-expanding scaffolds with cutting elements mounted thereto and balloon catheters insertable within the scaffold to radially expand the cutting elements against a stenotic lesion." Spec. 1, ll. 10–12.

CLAIMS

Claims 1–12 and 14–20 are on appeal. Claim 1 is illustrative of the appealed claims and recites:

> 1. A medical device assembly for incising a stenosis in a blood vessel, the medical device assembly comprising:
>
> a self-expanding scaffold configured to be expandable from a first contracted configuration to a second expanded configuration, the self-expanding scaffold being biased toward the second expanded configuration;
>
> a cutting element secured to the self-expanding scaffold and extending radially outward therefrom;
>
> a sheath having a lumen therein, the self-expanding scaffold positionable in the lumen of the sheath in the first contracted configuration;
>
> an elongate member extending proximally from the self-expanding scaffold through the lumen of the sheath;
>
> an inflatable balloon mounted on a catheter slidably disposed within the lumen of the sheath; and
>
> a guidewire disposed within the lumen of the sheath;
>
> wherein the self-expanding scaffold is constrained by the sheath to maintain the self-expanding scaffold in the first contracted configuration in the lumen of the sheath, and deployed out of the lumen of the sheath to permit the self-expanding scaffold to expand to the second expanded configuration.

Appeal Br. 32.

REJECTIONS

1. The Examiner rejects claims 1–3, 12, 14, and 17–19 under 35 U.S.C. § 103(a) as unpatentable over Sciver[3] in view of Appling.[4]
2. The Examiner rejects claims 4–6, 15, and 20 under 35 U.S.C. § 103(a) as unpatentable over Sciver in view of Appling and Uflacker.[5]
3. The Examiner rejects claims 8 and 9 under 35 U.S.C. § 103(a) as unpatentable over Sciver in view of Appling and Lukic.[6]
4. The Examiner rejects claims 10 and 11 under 35 U.S.C. § 103(a) as unpatentable over Sciver in view of Appling, Lukic, and Stinson.[7]
5. The Examiner rejects claims 7 and 16 under 35 U.S.C. § 103(a) as unpatentable over Sciver in view of Appling and Nott.[8]

DISCUSSION

Obviousness over Sciver and Appling

With respect to claim 1, the Examiner finds that Sciver teaches a device for incising a stenosis including a self-expanding scaffold, a cutting element, a sheath, an elongate member, and a guidewire as claimed. Final Act. 2 (citing Sciver Figs. 2B, 3A, 3B; col. 3, ll. 1–13; col. 4, ll. 8–16). The Examiner acknowledges that Sciver does not disclose an inflatable balloon as claimed, but the Examiner finds that "Sciver does disclose that other

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[3] Sciver, US 6,036,708, iss. Mar. 14, 2000.
[4] Appling et al., US 7,131,981 B2, iss. Nov. 7, 2006.
[5] Uflacker et al., US 2006/0173487 A1, pub. Aug. 3, 2006.
[6] Lukic et al., US 5,709,703, iss. Jan. 20, 1998.
[7] Stinson, US 7,127,789 B2, iss. Oct. 31, 2006.
[8] Nott et al., US 6,013,093, iss. Jan. 11, 2000.

instruments . . . are slidably disposed within the sheath and scaffold to aid in removal of stenosed tissue." Final Act. 2 (citing Sciver col. 3, ll. 13–22; col. 5, ll. 36–60). The Examiner further finds that Appling discloses an assembly for incising stenosis including an expandable scaffold, cutting elements, a tubular sheath, and an inflatable balloon. Final Act. 2–3 (citing Appling Figs. 2A, 2B, 3A, 12; col. 8, ll. 1–13; col. 11, ll. 1–19). Also, the Examiner finds and concludes:

> Appling further teaches that the balloon may aid in properly positioning cutting elements in certain situations wherein the lumen of the lesion is too tight or small to allow space for the wires to deploy (column 11, lines 40-50). As known in the art, lesions exist in a wide range of sizes and shapes due to variances in patient anatomy, health, and the particular medical condition. In light of Appling's teachings, one of ordinary skill in the art would have found it obvious to combine a balloon catheter with the Sciver assembly so that it is slidably disposed within the sheath lumen, in order to enhance the ability of the cutting elements to be properly deployed within a variety of lesions so that its performance is optimized for different patient needs.

Final Act. 3.

We agree with and adopt the Examiner's findings and conclusion regarding Sciver and Appling with respect to claim 1. As discussed below, we are not persuaded of reversible error by Appellants' arguments.

Appellants first argue that there is no reason to add a balloon to Sciver's device because it would not aid in the removal of stenosed tissue. Appeal Br. 11. In support, Appellants assert that outward radial expansion in Sciver is limited to contacting a permanent stent and adding a balloon would not allow for ease of expansion of the vessel because that purpose cannot be achieved with the permanent stent. *Id.* We disagree and find that the Examiner has provided sufficient reasoning to support the conclusion of

obviousness. In particular, the Examiner not only finds that Appling teaches the use of a balloon to ease expansion of a vessel but also that Appling teaches the balloon aiding in positioning of cutting elements, which would enhance the ability of cutting implements to be deployed. We are not persuaded that Sciver's teaching of a permanent stent would nullify the proposed reasoning for the combination. In short, the Examiner has identified certain advantages that may be obtained, as taught by Appling, and we are not persuaded of any incompatibility between the relied-upon teachings of Appling and the fact that Sciver discloses the use of a device within a permanent stent. Finally, we agree with the Examiner's response that "[e]xpanding a balloon to aid in expanding the scaffold (40) of Sciver would aid in penetrating a stenosis (14) (Figure 3B of Sciver) that is resistant or has a geometry preventing proper deployment of the scaffold." Ans. 9.

Next, Appellants argue that adding a balloon to Sciver or substituting a balloon for the other instruments in Sciver would render Sciver's device unsuitable for its intended purpose. Appeal Br. 12–13. In support, Appellants first assert that pushing the scar tissue outward through the permanent stent would not leave any tissue to be cut and removed. *Id.* However, we agree with the Examiner's response to this point. In particular, "[o]ne of ordinary skill in the art would recognize the benefit of combining the balloon taught by Appling with the Sciver scaffold to aid in expanding the scaffold outwardly to fracture and/or cut a resistant stenosis, therefore allowing the wires of the scaffold to penetrate into the thickness of the lesion so that the step of removing the lesion with the screw (36) may be performed." Ans. 10. As such, the addition of the balloon as proposed by

the Examiner would aid in using Sciver's device to remove tissue and would not render it inoperable for that purpose.

Appellants also assert with respect to this argument that the addition of the balloon would interfere with the other instruments provided in Sciver's device, e.g. the screw, coil, or ring. Appeal Br. 12. Along the same lines, Appellants assert that the Examiner erroneously found that Sciver's instruments are separate from the scaffold and inserted into the vessel separately. *Id.* 13. We also agree with the Examiner's response to these points. Specifically, one of ordinary skill in the art would have found it obvious to deploy the balloon as needed in a separate step so as not to interfere with the other instruments, and we consider any required modification to Sciver's device to implement the balloon as proposed to be well within capabilities of a person of ordinary skill in the art. As the Examiner states, "[b]alloon catheters exist in a wide variety of shapes and sizes for various types of procedures and combinations with a wide range of instruments, so one of ordinary skill in the art would have been capable of configuring a balloon catheter for insertion within the sheath lumen." Ans. 11.

Next, Appellants argue that Appling "fail[s] to teach a balloon catheter disposed within the lumen of a sheath, where the sheath meets the limitations of the pending claim(s)" and that Sciver also fails to teach this configuration. Appeal Br. 13. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. *See In re Keller*, 642 F.2d 413, 426 (CCPA 1981); *In re Merck & Co.*, Inc., 800 F.2d 1091, 1097 (Fed. Cir. 1986). Here, Appellants' argument is unpersuasive because the Examiner does not rely on

either Appling or Sciver individually to disclose the claimed balloon disposed within the lumen of the sheath. Rather, the rejection relies on the proposed combination for this element.

Finally, Appellants argue that "[t]here has been no persuasive evidence presented to show that the stent 40 of Sciver is in some way inadequate for its stated purpose," and thus, "there is no reason to make the proposed modification, which appears to merely solve a problem that does not exist, except for the teachings of Appellants' own disclosure, reliance upon which is clearly improper." Appeal Br. 14. However, we agree with the Examiner that "Sciver is not required to describe deficiencies of his own device, as Appling is relied upon for providing motivation for the combination by describing various benefits for expanding a cutting scaffold with a balloon." Ans. 12. Further, to the extent Appellants are arguing that the rejection is based on hindsight, we see no indication that the rejection is based on knowledge gleaned only from Appellants' disclosure. *See In re McLaughlin*, 443 F.2d 1392, 1395 (CCPA 1971).

For these reasons, we are not persuaded of reversible error, and thus, we sustain the rejection of claim 1.

Claim 2

With respect to claim 2, the Examiner maintains that "both Sciver and Appling disclose [that] the scaffold defines a proximal opening providing passage of a balloon catheter." Final Act. 3. Appellants argue that "Sciver fails to teach a balloon in conjunction with the disclosed cutting stent." Appeal Br. 14. However, we do not read the Examiner's statement as a finding that Sciver teaches a balloon as the rejection of independent claim 1 clearly acknowledges that Sciver does not disclose a balloon and relies on

Appling for the balloon. Thus, we are not persuaded of error with respect to claim 2 for this reason and the reasons discussed above with respect to claim 1.

Claim 3

With respect to claim 3, the Examiner finds that "the distal end of the scaffold (40) of Sciver meet[s] the requirements of a distal tip, since it is capable of allowing passage of a guidewire (30) and is coaxial with the remainder of the scaffold (40)." Final Act. 3. Appellants argue:

> One of ordinary skill in the art, having possession of the instant application, would not recognize the distal end of the stent 40 of Sciver as corresponding to the claimed distal tip. When properly considered in view of the instant specification, Sciver fails to teach the claimed distal tip. Similarly, Appling et al. fail to teach an expandable scaffold includes a distal tip having a guidewire lumen therethrough.

Appeal Br. 15. We are not persuaded because this argument fails to provide any specific explanation as to why one of ordinary skill in the art would not recognize that Sciver includes a distal tip as claimed. Accordingly, we sustain the rejection of claim 3.

Claim 12

Appellants' arguments with respect to independent claim 12 are substantially the same as the arguments presented with respect to claim 1. *See* Appeal Br. 15–19. We find those arguments equally unpersuasive with respect to claim 12, and thus, we sustain the rejection of claim 12 for the same reasons.

Claim 14

Appellants' argument with respect to claim 14 is substantially the same as the argument presented with respect to claim 3. *See* Appeal Br. 20.

We are unpersuaded for the same reasons discussed above, and thus, we sustain the rejection of claim 14.

Claims 17–19

With respect to independent claim 17, Appellants first present arguments that are substantially the same as the arguments presented with respect to claims 1 and 12. *See* Appeal Br. 20–24. We find those arguments equally unpersuasive with respect to claim 17.

Additionally, Appellants argue that the Examiner erred in finding that Appling discloses withdrawing the sheath to deploy the self-expanding scaffold because Appling discloses only advancing the sheath distally relative to the cutting elements to deploy them. Appeal Br. 24–25. We are not persuaded of reversible error by this argument because the Examiner also finds, and we agree, that "Sciver discloses the steps of advancing the scaffold and withdrawing the sheath 38 so that it automatically expands." Final Act. 3 (citing Sciver Figs. 3A–B; col. 3, ll. 1–12). Thus, we find that the proposed combination of art renders the claimed withdrawing step obvious, regardless of whether Appling individually teaches such a step.

Accordingly, we sustain the rejection of claim 17. We also sustain the rejection of claims 18 and 19, for which Appellants do not provide separate arguments. *See* Appeal Br. 25.

Obviousness over Sciver, Appling, and Uflacker

Claim 4 depends from claim 3 and further requires "wherein the catheter includes a distal tip configured to contact the distal tip of the self-expanding scaffold when the inflatable balloon is properly positioned within the interior of the self-expanding scaffold."

With respect to claim 4, the Examiner states:

> Appling teaches the concept of configuring the scaffold (5) to define a distal tip that is contacted by the distal tip of the balloon catheter (24) (see Figure 11). Uflacker discloses another stenosis incising scaffold (12) configured to be positioned above an expandable balloon (16) (see Figure 1 and 2). Uflacker teaches a configuration wherein the balloon catheter (14) defines a distal tip (21) that contacts a distal tip (20) of the scaffold when the balloon is properly positioned within the scaffold (para 32). It would have been obvious to one of ordinary skill in the art at the time the invention was made to configure the scaffold of the modified Sciver device to have a distal tip that is contacted by the distal tip of the balloon catheter, as taught by Uflacker, as this modification merely involves a combination of known cutting scaffolds according to known methods to obtain a predictable result of an expandable stenosis incising instrument.

Final Act. 4–5.

We are persuaded of error by Appellants' argument that "Uflacker et al. fails to provide the teachings set forth by the Examiner." Appeal Br. 26. In particular, the rejection relies on a finding that the distal tip of Uflacker's balloon catheter contacts the distal tip of the scaffold. However, we agree with Appellants that Uflacker shows a balloon catheter 14 that extends distally past the balloon 16 such that the distal tip of the catheter is not configured to contact the distal tip of Uflacker's scaffold 12. *See* Uflacker Figs. 1, 2. Because the rejection relies on a mischaracterization of Uflacker's disclosure, we are persuaded of reversible error and we do not sustain the rejection of claim 4. For the same reasons, we do not sustain the rejection of claims 5, 6, 15, and 20, the rejection of which rely on the same erroneous findings with respect to Uflacker. *See* Final Act. 4–5.

Remaining Obviousness Rejections

With respect to the rejections of claims 7–11 and 16, Appellants argue only that the additional art relied upon by the Examiner does not remedy the

deficiencies in the rejection of the independent claims. *See* Appeal Br. 29–31. Having found no deficiencies in the rejection of the independent claims, we are also not persuaded of error in the rejections of these claims. Accordingly, we sustain the rejections of claims 7–11 and 16.

CONCLUSION

For the reasons set forth above, we conclude as follows.

We AFFIRM the rejection of claims 1–3, 12, 14, and 17–19 under 35 U.S.C. § 103(a) as unpatentable over Sciver in view of Appling.

We REVERSE the rejection of claims 4–6, 15, and 20 under 35 U.S.C. § 103(a) as unpatentable over Sciver in view of Appling and Uflacker.

We AFFIRM the rejection of claims 8 and 9 under 35 U.S.C. § 103(a) as unpatentable over Sciver in view of Appling and Lukic.

We AFFIRM the rejection of claims 10 and 11 under 35 U.S.C. § 103(a) as unpatentable over Sciver in view of Appling, Lukic, and Stinson.

We AFFIRM the rejection of claims 7 and 16 under 35 U.S.C. § 103(a) as unpatentable over Sciver in view of Appling and Nott.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED-IN-PART